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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,812	04/16/2004	Corey S. Goodman	18941H-002911US	1573

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EXAMINER	
CHERNYSHEV, OLGA N	
ART UNIT	**PAPER NUMBER**
1649	

MAIL DATE	DELIVERY MODE
02/07/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/826,812	GOODMAN ET AL.	
	Examiner	Art Unit	
	Olga N. Chernyshev	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-12,14,16,17 and 19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-12, 14, 16, 17 and 19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Claims 10, 16 and 17 have been amended and claims 13, 15, 18 and 20-28 have been cancelled as requested in the amendment filed on August 16, 2007. Following the amendment, claims 10-12, 14, 16, 17 and 19 are pending in the instant application.

Claims 10-12, 14, 16, 17 and 19 are under examination in the instant office action.

2. The Declaration of Goodman, Kidd, Mitchell and Tear filed on December 03 (signed by Goodman, Kidd and Tear) and December 05, 2007 (signed by Mitchell) under 37 CFR 1.131 is sufficient to overcome the McCarthy et al. reference (section 16 of Paper mailed on February 12, 2007).

3. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

4. Applicant's arguments filed on August 16, 2007 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Claim Rejections - 35 USC § 101

5. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claims 10-12, 14, 16, 17 and 19 stand rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial credible asserted utility or a well-established utility for reasons of record in section 7 of Paper mailed on February 12, 2007.

At p. 17 of the Response, Applicant traverses the rejection on the grounds that the "biological function for Robo in the regulation of nerve cell function and morphology" is provided at p. 3, line 4 of the specification. Applicant submits that the specification teaches that antibodies to Robo "can be used, e.g., in applications where pathology relates to improper or undesirable axon outgrowth, orientation or inhibition thereof [p. 13, lines 10-19]". Applicant further refers to "experimental evidence that robo is involved in axon growth" in examples "showing that robo is expressed on longitudinally-projecting growth cones and axons (page 29, lines 12-17)". Applicant's arguments have been fully considered but are not persuasive for the following reasons.

At p. 3, the instant specification states that "Robo polypeptides can regulate cell, especially nerve cell, function and morphology". However, the evidence of record is inadequate to support this statement. The instant claims are directed to antibodies that specifically bind a human polypeptide of SEQ ID NO: 8 but the experimental data that Applicant refers to are limited to the disclosure of tissue distribution of a different Robo polypeptide in the *Drosophila* Embryo (p. 29 of the specification). Furthermore, the instant specification fails to present any scientific reasoning to support the asserted utility of using the anti-human Robo antibodies "for pharmaceutical development and diagnostic and therapeutic purposes [...] and/or for the treatment of pathology, wound repair incompetency or prognosis that is associated with improper or undesirable axon outgrowth, orientation and inhibition thereof" (p. 18 of the Response) solely based on the pattern of tissue staining of the insect Robo polypeptide of *Drosphila* species. There appears to be no factual evidence disclosed in the specification as filed or brought forward during the prosecution to support a conclusion that any protein that is "regionally" expressed (p.

29) or differentially expressed during embryonic development becomes immediately useful for "the treatment of pathology" associated with that tissue.

At pp. 19-20 of the Response, Applicant submits "additional evidence to support the contention that one of skill would believe that robo-related compositions are useful for identifying modulators that can be used in disease or conditions involving axon growth" by citing two articles published in 2002 and 2005. Applicant is advised that since the instant application claims priority to 1997, then the novelty and enablement of the instant invention is assessed as it is at the time of filing of 1997. It is a matter of law that the invention must be patentable at the time that an application is filed. Applicant may not rely upon subsequent discoveries to complete the claimed invention. In the decision *In re Lundberg*, 117 USPQ 190, 1958, the CCPA held that "advantages which are not disclosed in application cannot be urged as basis for allowing claims".

In order to satisfy the enablement requirement of section 112, an applicant must describe the manner of using the invention "in such full, clear, concise and exact terms as to enable any person skilled in the art ... to make and use the same..." 35 U.S.C §112, paragraph 1. Thus, the invention must be enabled at the time of filing and, therefore, the enablement cannot be supported by later obtained experimental results. *In re Rasmusson* Court held that

"If mere plausibility were the test for enablement under section 112, applicants could obtain patent rights to "inventions" consisting of little more than respectable guesses as to the likelihood of their success. When one of the guesses later proved true, the "inventor" would be rewarded the spoils instead of the party who demonstrated that the method actually worked. That scenario is not consistent with the statutory requirement that the inventor enable an invention

rather than merely proposing an unproved hypothesis". *In re Rasmusson v. SmithKline Beecham Corp.* 75 USPQ2D 1297, p1301.

Moreover, it is also a matter of law that the claimed invention must be useful in currently available form, which precludes any further experimentation to establish the utility of the claimed invention. In the instant case, the specification does not provide a single piece of evidence or line of reasoning which would support any role for the polypeptide of SEQ ID NO: 8 in any of the "conditions relating to abnormalities of axon growth" (p. 20 of the Response). There is nothing in the specification, as filed, which would lead an artisan to conclude that the polypeptide of SEQ ID NO: 8 plays any role in the plurality of diseases and disorders identified in the instant specification as related to "improper or undesirable axon outgrowth, orientation or inhibition thereof (p. 13 of the disclosure). Thus, the Robo polypeptide of SEQ ID NO: 8 as well as the instantly claimed antibodies that bind to it are only available as objects of future research and subsequently do not have a "real world" utility.

§101 requires a utility that is "substantial", i.e., one that provides a specific benefit in currently available form. *Brenner*, 383, U.S. at 534-35, 148 USPQ at 695. *Brenner's* standard has been interpreted to mean that "vague, general disclosures or arguments of "useful in research" or "useful as building blocks of value to the researcher" would not satisfy §101. See *Kirk*, 376 F. 2d at 945 153 USPQ at 55 (interpreting *Brenner*).

Thus, the record does not support Applicant's position that the characterization of tissue expression of Robo polypeptides during embryonic development would have suggested a specific biological function, or any other basis for patentable utility for the antibodies that bind to polypeptide of SEQ ID NO: 8, to a person skilled in the art at the time the application was filed.

In the terms used by the *Brenner* Court, such a characterization does not provide a specific utility in currently available form.

The specification provides no meaningful guidance regarding how to use information on tissue pattern expression in any practical way. The specification provides no guidance on how such information would allow those skilled in the art to use the claimed antibodies in a specific substantial way. As such, Applicant claims a product asserted to be useful "for identifying modulators of robo function, which modulators can be used for treating conditions relating to abnormalities of axon growth" (p. 20 of the Response), but the specification does not disclose how to interpret the data limited to localization of the other proteins that belong to Robo family to use the claimed antibodies "for treating conditions".

The Supreme Court noted that the patent system contemplates a basic quid pro quo: in exchange for the legal right to exclude others from his invention for a period of time, the inventor discloses his invention to the public. See *Brenner* 383 U.S. at 534, 148 USPQ at 695. The *Brenner* Court held that the grant of patent rights to an applicant is justified only by disclosure of an invention with substantial utility – a specific benefit in currently available form. Until the invention has been refined and developed to this point, the Court held, the applicant has not met his side of the bargain, and has not provided a disclosure that justifies granting him the right to exclude others. See *id.*

Therefore, since the instant specification does not disclose a credible "real world" use for the antibody that binds naturally occurring human protein of SEQ ID NO: 8 in their currently available form, then the claimed invention is incomplete and, therefore, does not meet the requirements of 35 U.S.C. § 101 as being useful, and the instant rejection is maintained.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 10-12, 14, 16, 17 and 19 also stand rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Conclusion

9. No claim is allowed.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey J. Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Olga N. Chernyshev, Ph.D.
Primary Examiner
Art Unit 1649

February 05, 2008